

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION

No. 5:09-CR-40-BR

UNITED STATES OF AMERICA )  
 )  
 v. ) **UNITED STATES' SENTENCING**  
 ) **MEMORANDUM AND MOTION FOR**  
 PHILIP JOE GUYETT, JR. ) **UPWARD DEPARTURE**

The United States of America, by and through the United States Attorney for the Eastern District of North Carolina, files this sentencing memorandum (1) addressing objections to the Pre-Sentence Report (PSR), and (2) moving for an upward departure and variance.

**Background and Details of the Crime**

**I. The Criminal Information**

On February 5, 2009, The United States Attorney for the Eastern District of North Carolina filed a Criminal Information alleging three counts of mail fraud against defendant Guyett. D.E. 1. The Information explains that defendant Guyett, acting through the corporate identify "Donor Referral Services, Inc.," removed human tissue from deceased donors at funeral homes in and around the Eastern District of North Carolina and provided such tissue, for a fee, to various tissue banks for subsequent sale to medical facilities and the eventual implantation in medical patients throughout the United States. Id.

As the Criminal Information explains, defendant Guyett would alter, omit, fabricate, and falsify material on the medical reports regarding these deceased donors, including the deceased donors' age

at death, their cause of death, and their having suffered from infectious or communicable diseases, so that the tissue would not be rejected by various tissue banks and defendant Guyett would be compensated. Id. at 2. On March 9, 2009, defendant Guyett pleaded guilty to the charges alleged in the Criminal Information. D.E. 7-9.

## **II. The FDA Report**

A report prepared by the United States Food and Drug Administration's Center for Biologics Evaluation and Research provides further detail into defendant Guyett's criminal scheme. See Report, attached as Exhibit A. The FDA inspection and investigation revealed that defendant Guyett failed to (1) create and maintain accurate records of donor screening; (2) screen donors or tissues by reviewing relevant medical records; (3) establish, maintain, and follow appropriate procedures for the tissue collecting steps he performed; (4) maintain all records of donor recovery, screening, and testing; and (5) establish, maintain and follow standard operating procedures to assure that recovery of tissue took place in a suitable environment that would not cause contamination or cross-contamination during recovery or increase the risk of spread of disease. Id. at 6. While tissue banks ("processors") made the final determination of donor eligibility, "the processors relied on the veracity of the manufacturing steps that Mr. Guyett had contracted with them to perform, and on the

accuracy and truthfulness of the donor records and test results he provided to them for that purpose.” Id. at 5.

The Report goes on to identify some of the most egregious misrepresentations that defendant Guyett undertook. For example, defendant Guyett hid from tissue banks and the consuming public that one particular donor suffered from liver cancer and chronic Hepatitis C. Id. at 8. He used blood samples from non-infected donors in order to secure “clean” test results for donors with various infections, or would simply alter test results that were returned indicating disqualifying infections. Id. at 10.

Defendant Guyett would also alter or omit risk factors in donors for communicable diseases. For one donor who died in a Las Vegas hotel room from methadone and opiate intoxication, defendant Guyett stated he died from a collapse at home. Id. at 11. For another donor, he hid evidence of the donor’s IV drug abuse, generally a disqualifying risk factor. Id.

Defendant Guyett also lied when representing to tissue banks and the outside world that he was abiding by the standards promulgated by the American Association of Tissue Banks, as he had contractually bound himself to do. This portion of the scheme is especially relevant in regard to donors that had cancer. While the presence of cancer is not a per se cause for ineligibility, it does lead to further scrutiny of tissue from that donor, as well as more research into medical treatment that donor received while alive.

See American Association of Tissue Bank Standards, Section D4.340 (10th and 11<sup>th</sup> editions) (stating donors with current or prior diagnosis of malignancy shall for suitability, with such evaluation to include the type of malignancy, clinical course and treatment prior to acceptance of a donor). Certified death records of 25 donors state that the cause of death or a contributing factor was cancer. Report at 13. For all of these, defendant Guyett indicated causes of death other than cancer. On the medical assessment form he used, he indicated "no" for questions regarding cancer or malignant disease. Id.<sup>1</sup>

Perhaps most frighteningly, the Report notes that the violations it references "only represent those that could be identified by a review of records. Mr. Guyett may have committed other violations that a review of records would not identify." Id. at 14. This point is exacerbated by the fact that defendant Guyett failed to keep and maintain accurate records that could have been subject to further review. Records reveal that 2,600 products manufactured from human tissue provided by defendant Guyett were distributed in domestic and foreign commerce, and at least 785 were implanted into human recipients. Id. at 14. Through investigation, 127 patients have been identified in the United States that had tissue implanted in them from a donor about whom

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<sup>1</sup>He did the same for six donors with Alzheimer's/Dementia and two donors with sepsis, both conditions that would likely preclude tissue from use under AATB standards. Id.

defendant Guyett had put forward some material falsification or omission regarding their relevant medical history.

### **Objections**

#### **I. Loss Amount**

Defendant Guyett objects to the use of \$391,392 as the loss amount in this case. Primarily, he asserts that (1) some of this money was earned while he and his company were operating in Las Vegas and (2) that some of this money was derived from his harvesting of tissue about which he did not make any false statements. In regard to the first argument, his operation of Donor Referral Services in Las Vegas constitutes relevant conduct pursuant to Section 1B1.3(a)(2) of the United States Sentencing Guidelines. Some of the false statements made by defendant Guyett involve tissue that was procured in Las Vegas. By way of one example, donor E04-11, who died of methadone and opiate intoxication in a hotel room in Las Vegas, was harvested by defendant Guyett in Las Vegas, not North Carolina. See Report at 11. Likewise, defendant Guyett took tissue from many of the donors whose cancer or sepsis he tried to conceal in 2004, when he was operating in Las Vegas. Id. at 13.

In regard to his second argument, Defendant Guyett's efforts to exclude profit for tissue that he did not have to lie about from the loss amount is also without merit. While the Fourth Circuit does have cases such as United States v. Parsons, 109 F.3d 1002

(4th Cir. 1997) in which the loss amount from "false" travel voucher submissions could easily and properly exclude the dollar value of accurate submissions, the case at bar is entirely distinct. Because of the regulations governing this very sensitive industry, defendant Guyett's lies led to recalls of **all** tissue collected by his company. See FDA Announcement, Attached as Exhibit B. Once the criminal conduct became known, the value of any and all tissue procured by Donor Referral Services became worthless. Other cases dealing with tainted consumer products have reached the same conclusion in assessing loss amounts. United States v. Gonzalez-Alvarez, 277 F.3d 73, 78-79 (1st Cir. 2002) (loss amounts includes value of all milk in same silos as tainted milk); United States v. Roggy, 76 F.3d 189, 193 (8th Cir. 1996) (holding that where the defendant applied an illegal pesticide to raw oats he was properly held responsible for not only the oats he sprayed, but also those oats that were indirectly considered contaminated by being at the same facilities as the sprayed oats); United States v. West, 942 F.2d 528, 531-32 (8th Cir. 1991) (holding, in case involving meat adulteration, that proper calculation of loss included the value of "good" meat that was mixed with the adulterated meat provided by the defendant). Accordingly, all proceeds collected by defendant Guyett during the commission of this offense should be considered as loss.

## **II. Number of Victims**

Defendant Guyett next asserts that there are only four victims in this case, the four tissue banks with whom he worked, and that the 127 patients who were implanted with tissue from donors whose medical histories the defendant lied about should not be included. These patients paid for, and underwent, procedures in which they very reasonably expected to have an allograft placed in them that was procured in compliance with FDA regulations and that adhered to minimal FDA requirements regarding suitability for human implantation. They did not get what they bargained for. Instead, after being notified of defendant Guyett's crime, many of these patients underwent testing to ensure that no communicable diseases were spread to them. Finally, at least one victim contracted a staff infection that his doctor believes derived from defendant Guyett's unsanitary procurement of tissue. See Memorandum of Interview, attached as Exhibit C. This victim has had follow-up surgeries with a resulting cost of ten of thousands of dollars.

## **III. Reckless risk of Seriously Bodily Injury**

Defendant Guyett asserts that this enhancement should not apply because the tissue banks made the final determination as to whether tissue was suitable for implantation. This objection is without merit. First, pursuant to regulation and contract, defendant Guyett was charged with compiling a medical history and taking a blood sample of the donors. Tissue banks relied on the

data that Guyett provided them, these medical histories and blood samples, to conduct their own final evaluation. See FDA Report at 5.

In addition to the risk of infection that defendant Guyett incorrectly argues could have been identified later in the process, defendant Guyett risked death and physical injury for his victims in other ways. As the declaration of Dr. Douglass Dirschl, Chief of Orthopaedics at UNC Hospitals, explains, utilizing either bone or tissue allografts from patients who are too old, or from patients who suffered from infection or diseases such as cancer, can impact the strength of the tissue or bone in question, and thus increase the possibility of a procedure failing. See Dirschl Declaration, attached as Exhibit D. For procedures dealing with critical areas such as the spine, such failures could result in death. Id. Further, many structural weaknesses cannot be identified through either visual inspection or even x-ray. Id. Accordingly, no one but defendant Guyett knew the harm to which he was exposing these patients.

#### **IV. Vulnerable Victims**

This objection is properly addressed by the probation officer and will also be addressed at the hearing.

#### **V. Scoring of Previous Conviction**

The probation officer correctly deals with this objection.



## **VI. Grounds for Upward Departure**

To be discussed below.

## **VII. Abuse of a Position of Trust**

The United States argues that the offense level should be increased by two points under section 3B1.3 of the Guidelines because the defendant abused a position of trust. Under the governing regulatory framework, procurers of tissue stand at the front line of quality control and in ensuring that the tissue implanted in patients around the country is safe. The information obtained by these procurers - the medical histories, the blood samples, the interviews with next of kin - are used throughout the rest of the manufacturing and implantation process to ensure safety. Defendant Guyett abused this position of trust. Like the mine operator in United States v. Turner, 102 F.3d 1350, 1360 (4th Cir. 1996), "society ha[s] to publically trust" that men like defendant Guyett who work on the front lines of highly-regulated fields impacting public health will choose to be worthy of that responsibility. Defendant Guyett abused that trust.

### **Departures and Variances**

The United States believes that a term of imprisonment of at least seven years is required in this case and that the Court should grant an upward departure and/or variance to achieve such a sentence.

After resolving objections to the PSR, the Court should next consider any appropriate grounds for departure under the guidelines. The most obvious grounds for departure is for extreme psychological injury under section 5K2.3. The letters of some of the victims who were implanted with the tissue in question are attach as Exhibits E through G, and document their psychological distress.

The defendant's risk to public health also warrants a departure under section 5K2.14 of the guidelines. His actions and the subsequent recall have had implications across the nation and the health of hundreds of patients were put at risk. Indeed, the heinous and cruel nature of his crimes is in itself grounds for an upward departure under section 5K2.8 for extreme conduct.

The United States contends that these traditional departures should raise the guidelines range up to 84 months. If the Court disagrees, the United States also moves for an upward variance to impose such a sentence. As will be argued more fully at the sentencing hearing, the factors laid out under Title 18, United States Code, Section 3553(a) counsel strongly towards such a variance. The heinous nature of this crime nearly speaks for itself, defendant Guyett's past run-in with the law did nothing to curtail his criminal activity, and others must be deterred from taking such egregious risks with other peoples' lives in the future.

For these reasons, the United States respectfully submits that a sentence including a term of imprisonment of 84 months be imposed.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I have this 1st day of October, 2009,  
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